AUG - 3 2001

Attachment 10

K011447

510(k) Summary
for the
Siemens In Space 3D Software Option

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

10 May, 2001

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Mr. Praveen Nadkarni
Phone: (732) 321-4950 Fax: (732) 321-4841

2. Device Name and Classification:

Trade Name:	In Space 3D Software Option
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class I.I.
Product Code:	90JAA

3. Substantial Equivalence:

The In Space 3D software option is designed for three-dimensional evaluation of data acquired with a standard angiographic C-arm devices. The package is substantially equivalent to the following device:

Device Name	*FDA Clearance Number*	*FDA Clearance Date*
3D Angio Software Option	K984634	03/12/99
Siemens Siremobil Iso C 3D Imaging Option	K003266	10/18/00
Philips Integris 3D RA Option	K983877	12/21/98

4. **Device Description:**
The In Space 3D package is a x-ray imaging software option which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

5. **Intended Use of the Device:**
The In Space 3D package are intended to assist the physician in skeletal and soft tissue imaging in addition to the originally approved indications.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
The Siemens In Space 3D software option and Philips Integris 3D-RA software allow construction of a three-dimensional model from two dimensional images acquired during rotational angiography.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Mr. Praveen Nadkarni
Technical Specialist
Siemans Medical Systems, Inc.
186 Wood Ave. South
ISELIN NJ 08830

Re: K011447
In Space 3D (Angiographic X-ray System Accessory)
Dated: May 10, 2001
Received: May 11, 2001
Regulatory Class: II
21 CFR 892.1600/Procode: 90 JAA

Dear Mr. Nadkarni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Attachment 11

Indications For Use

510(k) Number (if known): K011447
Device Name: **In Space 3D Software Option**

Indications For Use:

The In Space 3D package is a x-ray imaging software option which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

The In Space 3D package is intended for imaging both hard and soft tissues as well as other internal body structures(eg. Lesions, Stent implants) for diagnosis, surgical planning, interventional procedures and treatment follow-up.

As with the FDA cleared 3D Angio software package(K984634), this software package will also assist the physician in diagnosis and treatment of vessel malformations(i.e. Aneurysms, AVMs and Stenoses).

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David C. Seguss

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011447

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)